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| 10/659,980      | 09/10/2003  | Timothy A. Hovanec   | P 0284781 081289    | 6075             |

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EXAMINER

SALMON, KATHERINE D

|          |              |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
|----------|--------------|

1634

DATE MAILED: 05/22/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

10/659,980

Applicant(s)

HOVANEC, TIMOTHY A.

Examiner

Katherine Salmon

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 March 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 8-14 and 22-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-7 and 15-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 23 January 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 6/04, 10/03, 9/03.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Group 1, Claims 1-7 and 15-21, and Seq ID No. 5 in the reply filed on 3/09/2006 is acknowledged.

The traversal is on the grounds that the applicant asserts the subject matter of Groups I, II, and III are sufficiently related and are all based on nucleotide sequences of saltwater ammonia-oxidizing bacterial strains (p. 9 of reply). Applicant asserts that SEQ ID No. 5 and No. 8 should be rejoined because they are derived from a Markush group and the members of the group possess at least one property in common (p. 9 of reply). The applicant further asserts that it is not a burden to search up to ten sequences (p. 10 of reply).

This is not found persuasive because though Groups I, II, and III are drawn to a method for determining the quantity of bacteria that oxidize ammonia to nitrate using a probe, each group is drawn to distinct sequences. The probe used in Group III does not detect the target group of Group I and II and vice versa (p. 28 Table 10 of instant specification). Though the sequences all share a common element in which that are from ammonia oxidizing bacteria, each sequence is structurally different and the probes which hybridize to them are distinct. Searching more than one patentably distinct sequence represents a serious burden for the office because each sequence is drawn to a structurally distinct chemical compound. The specification teaches two distinct phylogenetic relationships of bacterial sequences, SEQ ID No 1-4 (Figure 1) and Seq ID

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No. 18-20 (Figure 6). The search for ten sequences is a burden on the office because of the time it takes to fully search even one sequence.

With regard to the separation of SEQ ID No. 5 and 8, the argument has been fully reviewed but has not been found persuasive. SEQ ID No. 5 detects the bacteria sequences of Type A (SEQ ID 1 and 2). SEQ ID No. 8 detects the bacteria sequences of Type B (SEQ ID 3). These two probes are distinct sequences, which are used to detect sequences of different types of ammonia-oxidizing bacteria.

2. The requirement is still deemed proper and is therefore made Final.
3. Claims 8-14 and 22-28 are withdrawn from consideration as being drawn to a nonelected group.
4. Claims 29-32 have been cancelled.
5. An action on the merits of Claims 1-7 and 15-21 with regard to SEQ ID No. 5 is set forth below.
6. This application contains subject matter (SEQ IDs) drawn to an invention nonelected with traverse reply filed on 3/09/2006. A complete reply to the final rejection must include deletion of nonelected subject matter or other appropriate action (petition) (37 CFR 1.144) See MPEP § 821.01.

***Priority***

7. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied

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with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. [1] as follows:

Claims 15-21 are drawn to a method for detecting and determining comprising providing a detectably labeled probe that has at least 96% identity over the full length thereof to a nucleotide sequence as set forth in selected from the group consisting of SEQ ID No. 5. The specification of Application No. 09/573684 does not provide any teaches of at least 96% identity to SEQ ID No. 5. Therefore priority is not given for Claims 15-21 to Application No. 09/573684. Priority for Claims 15-21 is given to Provisionals 60/386217, 60/386218, and 60/386219 all filed 9/19/2002 because these provisionals teach a sequence identity of at least 96% to SEQ ID No. 5.

### ***Abstract***

8. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Correction of the first line "described herein are" is requested.

***Specification***

9. The disclosure is objected to because of the following informalities: In the "Brief Description of The Drawings" section the specification teaches that SEQ ID No. 4 is a substrain. In Figure 1, the bacterial strains are separated into three types, A, B, C. Seq ID No. 3 is a Type B, SEQ ID no. 4 is a Type C, and SEQ ID No. 1 is a Type A. Seq ID No. 2 is a Type A1. It seems that in the figure that SEQ ID No. 2 is a substrain not SEQ ID No. 4.

In the drawings Figures 1 and 6 do not show which sequences are SEQ ID Nos. It is difficult to determine the relationship among SEQ ID No. 1-4 because the SEQ IDs are not correlated with the actual names on the figures. The addition to the "Brief Description of Drawings" of the relationship of SEQ ID No. 1-4 with the type of bacteria would elevate the confusion.

***Claim Rejections - 35 USC § 112***

10. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 1-7 and 15-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 is drawn to providing a probe including a nucleotide sequence "as set forth" (line 5). It is unclear what "as set forth" means in regard to the claim. Claim 15 is drawn to providing a labeled probe to a nucleotide sequence "as set fourth in" (line 9). It is unclear what "as set forth in" encompasses.

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12. Claims 15-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are drawn to a detectably labeled probe that has at least 96% identity over its full length to SEQ ID No. 5. For a probe to have 96% identity to SEQ ID No. 5, which is 18 nucleotides in length, the probe must be at least 25 nucleotides in length. For probes smaller than 18 nucleotides in length the probes would have to have 100% identity. The limit of the size of the probes with regard to the limitation of 96% is unclear because it encompasses partial nucleotides.

***Claim Rejections - 35 USC § 102***

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

13. Claims 15-21 are rejected under 35 U.S.C. 102(a) as being anticipated by Hovanec et al. (WO 01/90312 A1 November 29, 2001).

Hovanec et al. teaches a method of detecting and measuring the amount of bacteria present in a medium (p. 14 lines 24-25). With regard to Claim 15, Hovanec et al. teaches using a probe (the same exact probe as SEQ ID No. 5 of the instant application) to detect type A AOB with the 16S rDNA nucleotide sequence of SEQ ID No. 1 and 2 (the same sequences as the instant application) (p. 14 lines 25-27).

Hovanec et al. teaches providing a detectably labeled probe; isolating total DNA from a medium, exposing the total DNA to a probe in which the probe hybridized only to the nucleic acid of the bacteria and detecting and measuring the hybridized probe for detecting and measuring the quantity of bacteria (p. 15 lines 20-27). With regard to Claim 16, Hovanec et al. teaches selecting a medium such as freshwater, seawater,

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and wastewater (p. 13 lines 8-10). With regard to 17, Hovanec et al. teaches the medium can include aquarium gravel, sponge filter material, filter floss, and plastic filter media (p. 16, lines 1-5). With regard to Claim 18, Hovanec et al. teaches that DNA can be isolated out of any of the taught medium (p. 16, lines 1-5). With regard to Claim 19, Hovanec et al. teaches the use of DNA chips (p. 15 line 10). With regard to Claim 20 and 21, Hovanec et al. teaches using a robocycler (RT PCR) to conduct a PCR experiment (p. 25 lines 1<sup>st</sup> paragraph).

### **Conclusion**

14. No claims are allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Katherine Salmon whose telephone number is (571) 272-3316. The examiner can normally be reached on Monday-Friday 8AM-430PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Katherine Salmon 5/12/2006*

Katherine Salmon  
Examiner  
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*Jehanne Sitton*  
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5/12/06